Paper No. 23

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte EBERHARD AMMERMANN, EARLE BUTTERFIELD, JENS LERCHL, GISELA LORENZ, ACHIM MOLLER, UDO RABE, RALF-MICHAEL SCHMIDT, and UDO CONRAD

Appeal No. 2003-1214
Application No. 09/403,654

ON BRIEF

Before ADAMS, GRIMES, and GREEN, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 29-36, 39, 41-46, and 49-51, all of the claims remaining.

Claims 29, 41, and 45 are the independent claims, and read as follows:

29. A process for the production of a methyl methoxyimino-α-(o-tolyloxy)-o-tolylacetate (BAS 490F)-tolerant plant, said process comprising transforming a plant with a gene encoding a methyl methoxyimino-α-(o-tolyloxy)-o-tolylacetate (BAS 490F)-binding polypeptide, whereby said polypeptide and the corresponding gene encoding said polypeptide is produced exogenously and isolated by the following steps:

a) immunizing an animal with methyl methoxyimino-α-(o-tolyloxy)-o-tolylacetate (BAS 490F) to produce a polyclonal serum of said polypeptide,

b) producing a monoclonal cell line to produce a specific, monoclonal methyl methoxyimino-α-(o-tolyloxy)-o-tolylacetate (BAS 490F)-binding polypeptide, [and]

c) isolating the mRNA encoding said monoclonal polypeptide of step b) from said monoclonal cells and synthesizing the corresponding cDNA encoding said polypeptide.

41. A process for the transformation of a plant or cells of a plant, said process comprising introducing a gene sequence which encodes a methyl methoxyimino-α-(o-tolyloxy)-o-tolylacetate (BAS 490F)-binding polypeptide into the plant or the cells of the plant.

45. A process for production of a methyl methoxyimino-α-(o-tolyloxy)-o-tolylacetate (BAS 490F)-binding polypeptide, said process comprising transforming a plant or cells of a plant with a gene which encodes such a polypeptide and subsequently isolating the polypeptide.

The examiner does not rely on any references.

Claims 29-36, 39, 41-46, and 49-51 stand rejected under 35 U.S.C. § 112, first paragraph, as nonenabled and inadequately described.

We affirm the rejection of claims 41-45, 49, and 50, and reverse the rejection of claims 29-36, 39, 46, and 51.

Background

"Chemical control of fungi in agronomically important crops requires the use of highly selective fungicides without phytotoxic effect. . . . However, in some cases, it is difficult to develop sufficiently selective fungicides which can be employed in all important large-scale crops of plants and which do not cause damage to the plant which provides the yield in any crop. The introduction of

fungicide-resistant or -tolerant crop plants can contribute to solving this problem." Specification, page 4.

The specification discloses a method for producing fungicide-tolerant plants. In its most general form, the method entails "expressing, in the plants, an exogenous polypeptide, antibody or parts of an antibody with fungicide-binding properties." Page 5. In one embodiment, the method comprises

(1) raising antibodies to the fungicide by immunizing a vertebrate with the fungicide coupled to a high molecular weight carrier (specification, page 5);

(2) generating hybridomas that produce monoclonal antibodies to the fungicide by fusing antibody-producing cells and cancer cells (id.);

(3) isolating cDNA encoding the monoclonal antibody and cloning it into an expression vector functional in plants (id., pages 5-10); and

(4) transforming plants with the antibody-encoding cDNA (id., pages 10-12).

The specification provides a working example of the above-described embodiment of the disclosed method. See pages 18-24.

Discussion

The claims are directed to methods of producing plants resistant to the fungicide BAS 490F. Claim 29 is directed to a process comprising transforming a plant with a gene encoding a BAS 490F-binding polypeptide, where that gene is defined by the following product-by-process limitations:

> said polypeptide and the corresponding gene encoding said polypeptide is produced exogenously and isolated by the following steps:
>
> a) immunizing an animal with [BAS 490F] to produce a polyclonal serum of said polypeptide,
>
> b) producing a monoclonal cell line to produce a specific, monoclonal [BAS 490F]-binding polypeptide, [and]

> c) isolating the mRNA encoding said monoclonal polypeptide of step b) from said monoclonal cells and synthesizing the corresponding cDNA encoding said polypeptide.

As a result of the product-by-process limitations, claim 29 is limited to a method comprising transforming a plant with cDNA encoding a BAS 490F-binding monoclonal antibody.

Claims 41 and 45, the other independent claims on appeal, do not contain the product-by-process limitations of claim 29. Claim 41 is directed simply to a process of transforming a plant that "compris[es] introducing a gene sequence which encodes a [BAS 490F]-binding polypeptide into the plant or the cells of the plant." Claim 45 is directed to a process of making a BAS 490F-binding polypeptide, "comprising transforming a plant or cells of a plant with a gene which encodes such a polypeptide and subsequently isolating the polypeptide."

The examiner rejected the claims as nonenabled and lacking an adequate written description.

1. Written description

The examiner rejected all of the claims as inadequately described. With respect to claim 29 and the claims that depend on it, the examiner noted that the specification only teaches "isolation of a single nucleotide sequence encoding a single monoclonal antibody (Example 2 on pages 19-20), but does not describe the resultant nucleotide sequence." Examiner's Answer, page 4. The examiner also noted that claims 41-45, 49, and 50 "encompass all BAS 490F-binding polypeptides" but lacked an adequate description for "genes encoding other binding polypeptides, which are not specifically antibody encoding genes." Id.

The examiner bears the burden of showing that the claims are not adequately described. See In re Alton, 76 F.3d 1168, 1175, 37 USPQ2d 1578, 1583 (Fed. Cir. 1996). To satisfy the written description requirement, the specification does not have to describe the invention in the same words used in the claims, but it must convey with reasonable clarity to those skilled in the art that the inventor was in possession of the invention. See Purdue Pharma L.P. v. Faulding, Inc., 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000).

We will start with claim 29. That claim defines the gene used to transform plants in product-by-process terms. A product can be described in terms of the process used to produce it. See, e.g., Fiers v. Revel, 984 F.2d 1164, 1169, 25 USPQ2d 1601, 1604-05 (Fed. Cir. 1993): "[I]n addition to being claimable by structure or physical properties, a chemical material can be claimed by means of a process. . . . Conception of a substance claimed per se without reference to a process requires conception of its structure, name, formula, or definitive chemical or physical properties" (emphasis added). The Fiers court was concerned with conception, not written description, but the court made clear that the two are closely related: "If a conception of a DNA requires a precise definition, such as by structure, formula, chemical name, or physical properties, as we have held, then a description also requires that degree of specificity." Id. at 1171, 25 USPQ2d at 1606. By analogy, then, if the process of making a product can suffice to show conception of that product, the process can also suffice to describe the product.

The examiner's rejection of claim 29, on the basis that the specification does not adequately define the DNA used in the claimed process, does not take into account the claim's product-by-process format. Nor is it consistent with the Federal Circuit's recent holding that not all functional descriptions are defective. See, e.g., Noelle v. Lederman, __ F.3d __, 2004 WL 77931 (Fed. Cir. Jan 20, 2004) ("[T]he written description requirement would be met for all of the claims [of the patent at issue] if the functional characteristic of [the claimed invention was] coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed") (quoting Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 965, 63 USPQ2d 1609, 1613 (Fed. Cir. 2002), bracketed material in original). The Noelle court held that "based on [the court's] past precedent, as long as an applicant has disclosed a 'fully characterized antigen,' either by its structure, formula, chemical name, or physical properties, or by depositing the protein in a public depository, the applicant can then claim an antibody by its binding affinity to that described antigen." Id.

We find that the product-by-process language used in claim 29, coupled with the description of that process in the specification, provides an adequate written description of the claimed process, including the DNA used therein. The rejection of claims 29-36, 39, 46, and 51 for inadequate written description is reversed.

Claims 41 and 45 are a different matter. These claims do not include a product-by-process limitation or otherwise limit the scope of the recited gene encoding a BAS 490F-binding polypeptide. Thus, as the examiner pointed out,

the claims are not limited to methods using DNA encoding a BAS 490F-binding monoclonal antibody. Rather, the claims read on methods of using any gene encoding a polypeptide that binds BAS 490F. The specification does not adequately describe this genus of polypeptide-encoding DNAs.

University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997), provides the appropriate analysis. The claims in Lilly were directed generically to vertebrate or mammalian insulin cDNAs. See id. at 1567, 43 USPQ2d at 1405. The court held that a structural description of a rat cDNA was not an adequate description of these broader classes of cDNAs, because a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name, ' of the claimed subject matter sufficient to distinguish it from other materials." Id. (bracketed material in original).

The Lilly court explained that

> a generic statement such as . . . 'mammalian insulin cDNA,' without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus.

Id. at 1568, 43 USPQ2d at 1406. Finally, the Lilly court set out exemplary ways in which a genus of cDNAs could be described:

> A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a

> recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.

Id.

The court recently revisited the issue of describing DNA. See Enzo Biochem, Inc. v. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court held that a claimed DNA could be described without, necessarily, disclosing its structure. The court adopted the standard that "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.'" See id. at 1324, 63 USPQ2d at 1613 (emphasis omitted, ellipsis and bracketed material in original).

While the inventions at issue in Lilly and Enzo were DNA constructs per se, the holdings of those cases are also applicable to the instant claims. Claims 41 and 45 are directed to methods, rather than products, but carrying out the claimed methods requires using a gene encoding a BAS 490F-binding polypeptide. Thus, the specification must adequately describe the gene needed to practice the claimed method; logically, a method of using a product cannot be adequately described without describing the product.

Thus, the instant specification may provide an adequate description of the generic genes recited in claims 41 and 45, per Lilly, by describing "structural

features common to the members of the genus, which features constitute a substantial portion of the genus." Alternatively, the specification can describe the genus by describing a "representative number" of genes encoding BAS 490F-binding polypeptides, where the representative species are described according to the standard of either Lilly or Enzo.

In this case, the specification does not describe generic genes encoding BAS 490F-binding polypeptides in accordance with either of the above standards. The specification discloses a method of making a gene encoding a monoclonal antibody that binds BAS 490F. See pages 5-12 and 18-24. Although the specification does not disclose the structure of the monoclonal antibody-encoding gene, we have concluded that the specification adequately describes the gene via its binding specificity and method of production. The specification provides no description of any other genes encoding BAS 490F-binding polypeptides.

The specification thus does not describe any structural features common to members of the genus of genes encoding BAS 490F-binding polypeptides. The specification's disclosure of genes encoding a BAS 490F-binding antibody does not suffice. The description of this single species provides no description of what structural features are common to genes encoding BAS 490F-binding polypeptides. Since the specification describes no common structural features, it necessarily does not describe structural features that "constitute a substantial portion of the genus," per Lilly.

The specification also does not describe a "representative number" of species within the genus to constitute a description of the full genus. Under either the Lilly or Enzo standard, the specification describes only a single species of a gene encoding BAS 490F-binding polypeptides. Appellants have provided no evidence to show that this single species is representative of the structures of the full genus of genes encoding BAS 490F-binding polypeptides. The only BAS 490F-binding polypeptides discussed in the specification are antibodies, either polyclonal or monoclonal, that specifically bind BAS 490F. No other BAS 490F-binding polypeptides are identified, nor does the specification disclose methods of making BAS 490F-binding polypeptides other than antibodies.

Thus, the evidence supports the examiner's position that a description of a single gene encoding a BAS 490F-binding monoclonal antibody is inadequate to describe the full genus of genes encoding BAS 490F-binding polypeptides encompassed by claims 41 and 45. Since the specification does not adequately describe the genes encoding BAS 490F-binding polypeptides required to practice the methods of claims 41 and 45, it does not adequately describe the claimed method.

Appellants argue that the specification describes a process of producing DNA encoding a BAS 490F-binding antibody. Appeal Brief, page 6. Appellants also argue that the "knowledge of a DNA sequence is not necessary to practice the invention, but rather the invention is practiced by carrying out the process steps set out in the claims." Id., page 8. Finally, Appellants cite the Reindl

declaration as evidence that those skilled in the art would have recognized the specification's description as adequate. Id.

These arguments do not overcome the rejection of claims 41-45, 49, and 50. The only BAS 490F-binding polypeptides that are disclosed in the specification are BAS 490F-binding antibodies. The specification does not even identify any other BAS 490F-binding polypeptides, much less describe the structure of their encoding genes. Since claims 41 and 45 do not contain the product-by-process limitations of claim 29, Appellants cannot rely on process limitations to provide the description required by case law. See Fiers, 984 F.2d at 1169, 25 USPQ2d at 1605 ("Conception of a substance claimed per se without reference to a process requires conception of its structure, name, formula, or definitive chemical or physical properties."); id. at 1171, 25 USPQ2d at 1606 ("If a conception of a DNA requires a precise definition, such as by structure, formula, chemical name, or physical properties, as we have held, then a description also requires that degree of specificity.").

The Reindl declaration also does not overcome the rejection. Dr. Reindl summarizes the method disclosed in the specification and concludes that "the invention itself includes process steps for isolating a nucleotide sequence and these steps would have been understood by the skilled worker in the field. Consequently, the disclosure of the nucleotide sequence is not necessary to make use of the invention."

We disagree. Dr. Reindl's conclusion is based on an understanding that the claimed method involves using a gene that is obtained by the following process:

> first immunizing an animal with the fungicide or herbicide to produce a polyclonal Serum of said polypeptide. A monoclonal cell line which produces the polypeptide is then produced. The mRNA encoding the polypeptide is then isolated and the corresponding cDNA is synthesized. Finally the cDNA is used to transform the plant.

Reindl declaration, pages 1-2. Claims 41 and 45, however, are not limited to using genes produced according to this process, nor are they otherwise limited to monoclonal antibodies that bind BAS 490F. The Reindl declaration is based on an incorrect understanding of the claimed subject matter, and we do not find it persuasive. The rejection of claims 41-45, 49, and 50 for inadequate written description is affirmed.

2. Enablement

The examiner also rejected all of the claims as nonenabled. Since we have already concluded that claims 41-45, 49, and 50 are not supported by an adequate description, we need not reach the issue of whether they are also nonenabled. As relevant to claim 29, the examiner reasoned that

> [t]he specification only provides guidance for a method of producing a BAS 490F-tolerant plant by transformation of a plant with a gene encoding an anti-BAS 490F antibody scFv fragment (see Example 2 on pages 19-20 of the specification). However, Appellant does not deposit the gene nor teach its nucleotide sequence, and hence Appellant does not provide sufficient guidance for another to practice the claimed invention.

Examiner's Answer, page 8.

Appellants argue that the claimed "process does not require knowledge of a DNA sequence, but rather the specification provides guidance as to how to obtain such a sequence and use it to transform a plant. The focus of the present invention is the unconventional method of isolating from an animal gene a sequence encoding an antibody which acts against herbicides/fungicides in plants. Concrete steps of this novel method of producing herbicide/fungicide resistant plants are disclosed in detail in the specification. . . . [O]ne of ordinary skill in the art would have understood the process steps involved and been able to make and use the invention." Appeal Brief, page 9.

The examiner bears the initial burden of showing that a claimed invention is not enabled. In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). To be enabling, the specification must allow those skilled in the art to practice the full scope of the claims without undue experimentation. See id. at 1561, 27 USPQ2d at 1513. "That some experimentation may be required is not fatal; the issue is whether the amount of experimentation required is 'undue.'" In re Vaeck, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991) (emphasis in original).

We agree with Appellants that the examiner has not shown that practicing the method of claim 29 would have required undue experimentation. The examiner has acknowledged that the specification shows a method of making a BAS 490F-tolerant plant by generating a single-chain antibody fragment from a gene encoding a BAS 490F-specific monoclonal antibody and transforming a plant with the BAS 490F-binding scFv fragment. See the Examiner's Answer,

page 8, which cites the specification's Example 2. That example also describes isolation of the antibody-encoding cDNA from the antibody-producing hybridoma. The specification indicates, and the examiner does not dispute, that production of hybridomas is routine in the art. See pages 18-19.

Thus, it appears that all of the steps required to practice the method of claim 29 are either exemplified in the specification or routine in the art. The examiner has not explained why undue experimentation would have been required to practice the method resulting from carrying out such steps sequentially. The only factor the examiner asserts as a basis for undue experimentation is that Appellants have not deposited or disclosed the sequence of the BAS 490F-binding antibody fragment used in the specification's Example 2. As Appellants point out, however, practicing the claimed method does not require knowing the DNA sequence of the antibody-encoding gene. Thus, the absence of such sequence information in the specification would not appear to increase the required experimentation at all.

The examiner presents no other fact-based explanation of why undue experimentation would have been required to practice the method of claim 29. Therefore, the examiner has not carried the initial burden of showing that claim 29 is nonenabled, and the rejection of claims 29-36, 39, 46, and 51 under 35 U.S.C. § 112, first paragraph, is reversed.

Summary

We reverse the rejection of claims 29-36, 39, 46, and 51 under 35 U.S.C. § 112, first paragraph, for inadequate written description and nonenablement. We affirm the rejection of claims 41-45, 49, and 50, for inadequate written description and do not reach the rejection of these claims for nonenablement.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED IN PART

Donald E. Adams)
Administrative Patent Judge)
)
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Eric Grimes) BOARD OF PATENT
Administrative Patent Judge) APPEALS AND
)
Lora M. Green) INTERFERENCES
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